

Notice of Allowability

Application No.

10/566,252

Examiner

Charanjit S. Aulakh

Applicant(s)

NAGASAWA ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Paper filed 11 January 2007.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

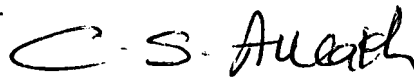
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 3/9/07.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


CHARANJIT S. AULAKH, PH.D
PRIMARY EXAMINER

The specification teaches inhibitory effect of instant compounds on NK-1 and NK-2 receptors in vitro (see tables 2-4 on pages 313-314). However, there is no teaching or guidance present in the specification how the instant compounds having inhibitory effect on NK-1 and /or Nk-2 receptors in vitro will have utility for treating irritable bowel syndrome, pain, anxiety, obstructive bronchial diseases, headache or vomiting following their in vivo administration. There is lot of unpredictability in correlating in vitro effect of a compound to its in vivo activity. It is well known in the art that in vitro activity does not necessarily correlate with in vivo activity of a compound since unlike in vitro activity, in vivo activity is affected by various factors such as absorption, metabolism and influence of hormones etc. There is no teaching either in the specification or prior art that hyperactivity of NK-1 and/or NK-2 receptors is implicated in the etiology of irritable bowel syndrome, pain, anxiety, obstructive bronchial diseases, headache or vomiting. There are no working examples present showing efficacy of instant compounds in known animal models of irritable bowel syndrome, pain, anxiety, obstructive bronchial diseases, headache or vomiting. There is no teaching in the specification or prior art references provided showing well known utility of structurally closely related compounds having inhibitory effects on NK-1 and/or NK-2 receptors in vitro for treating of irritable bowel syndrome, pain, anxiety, obstructive bronchial diseases, headache or vomiting. The instant compounds of formula (1) encompasses several hundreds of thousands of compounds based on the values of variables R1-R5, X1-X4, n1 and n2 and therefore, in absence of such teachings, guidance, presence of working examples, the state of the prior art and unpredictability, it would require undue experimentation to demonstrate the

DETAILED ACTION

1. According to paper filed on Jan. 11, 2007, the applicants have amended claims 1-9 and furthermore, have added new claims 10-12.
2. Claims 1-12 are now pending in the application.

EXAMINER'S AMENDMENT

3. The following amendment is pursuant to a telephone conversation with the applicant's attorney, Mr. Charles J. Andres on March 9, 2007. The following changes have been made in claims:

Cancel claim 12.

In claim 8, page 8, last line, after protecting group, insert --- ; ---- and furthermore, on page 9, insert ---- . ----- after last compound (1-b).

In claim 9, line 4, after anxiety, delete ---- , an obstructive bronchial disease, headache, -----.

4. Claims 1-11 are allowed since the applicants have amended claims to overcome indefiniteness rejections and furthermore, due to their persuasive arguments based on prior art knowledge of well known utility of numerous NK-1 and NK-2 receptor antagonists of diverse structures in treating irritable bowel syndrome, pain, anxiety and vomiting.

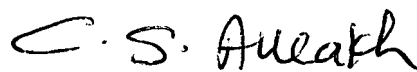
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

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(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charanjit S. Aulakh
Primary Examiner
Art Unit 1625